K091531

510(k) Summary

NOV 2 2009

Sponsor:

Choice Spine, LP
306 Erin Drive
Knoxville, TN 37919
ph: 865.246.3333 x4
fax: 865.588.4045

Contact:

G. Todd Hawkins
Director of Regulatory Affairs/Quality Assurance

Trade Name:

Choice Spine Cervical Interbody Spacer System

Common Name:

Intervertebral body (or interbody) fusion device

Classification & Name:

888.3080 – Intervertebral Fusion Device with Bone Graft, Cervical

Device Product Code:

ODP

Device Description:

The *Choice Spine Cervical Interbody Spacer System implants ("spacers")* have a basic oval shape with a hollow center for placement of bone graft. The superior and inferior surfaces have angled ridges, or "teeth," for resisting migration. The spacers are available in an assortment of heights and in multiple angles of lordosis to accommodate different anatomic requirements.

Intended Use:

The *Choice Spine Cervical Interbody Spacer System* is intended for anterior cervical spine intervertebral body fusion at one level from the C2-C3 disc to the C7-T1 disc for the treatment of degenerative disc disease (DDD) in skeletally mature patients who have had six (6) weeks of non-operative treatment. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is to be used with supplemental fixation and with autograft to facilitate fusion.

510(k) Summary (continued)

Materials:

The *Choice Spine Cervical Interbody Spacers* are manufactured from polyetheretherketone (PEEK-OPTIMA® polymer from Invibio®) as described by ASTM F2026. Integral radiopaque markers are manufactured from tantalum as described by ASTM F560.

Substantial Equivalence:

Documentation was provided that demonstrates the *Choice Spine Cervical Interbody Spacer System* to be substantially equivalent to previously cleared device systems. The substantial equivalence is based upon equivalence in intended use, indications, anatomic location, material, method of stabilization, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Choice Spine, LP
% Mr. G. Todd Hawkins
Director of Regulatory Affairs/QA
306 Erin Drive
Knoxville, Tennessee 37919

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Re: K091531
Trade/Device Name: Choice Spine Cervical Interbody Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: October 27, 2009
Received: October 28, 2009

Dear Mr. Hawkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091531

Device Name: ***Choice Spine Cervical Interbody Spacer System***

Indications for Use:

The *Choice Spine Cervical Interbody Spacer System* is intended for anterior cervical spine intervertebral body fusion at one level from the C2-C3 disc to the C7-T1 disc for the treatment of degenerative disc disease (DDD) in skeletally mature patients who have had six (6) weeks of non-operative treatment. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is to be used with supplemental fixation and with autograft to facilitate fusion.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091531